

Tezolin®

Tedizolid Phosphate

Tablet

Description

Tezolin® contains Tedizolid Phosphate, which is a synthetic antibacterial agent of the oxazolidinone class. Tezolin® tablets for oral administration contain 200 mg of Tedizolid Phosphate.

Indications

Acute Bacterial Skin and Skin Structure Infections

Tezolin® is an oxazolidinone-class antibacterial agent indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*) and *Enterococcus faecalis*.

Dosage and Administration

The recommended dosage of Tezolin® is 200 mg administered once daily for six (6) days orally (with or without food) in patients 18 years of age or older. If patients miss a dose, they should take it as soon as possible anytime up to 8 hours prior to their next scheduled dose. If less than 8 hours remain before the next dose, wait until their next scheduled dose.

Adverse Reactions

The most common adverse reactions (>2%) are nausea, headache, diarrhea, vomiting, and dizziness.

Use in Special Population

Pregnancy: Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Tezolin® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether Tedizolid is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Tezolin® is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 18 have not been established.

Geriatric Use: No overall differences in pharmacokinetics were observed between elderly subjects and younger subjects.

Drug Interaction

Monoamine Oxidase Inhibitors: Tedizolid is a reversible inhibitor of monoamine oxidase (MAO) *in vitro*. The interaction with MAO inhibitors could not be evaluated in Phase 2 and 3 trials, as subjects taking such medications were excluded from the trials. **Adrenergic Agents:** Two placebo-controlled crossover studies were conducted to assess the potential of 200 mg oral Tezolin® at steady state to enhance pressor responses to pseudoephedrine and tyramine in healthy individuals. No meaningful changes in blood pressure or heart rate were seen with pseudoephedrine. The median tyramine dose required to cause an increase in systolic blood pressure of ≥ 30 mmHg from pre-dose baseline was 325 mg with Tezolin® compared to 425 mg with placebo. Palpitations were reported in 21/29 (72.4%) subjects exposed to Tezolin® compared to 13/28 (46.4%) exposed to

placebo in the tyramine challenge study. Serotonergic Agents: Serotonergic effects at doses of tedizolid phosphate up to 30-fold above the human equivalent dose did not differ from vehicle control in a mouse model that predicts serotonergic activity. In Phase 3 trials, subjects taking serotonergic agents including antidepressants such as selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants, and serotonin 5-hydroxytryptamine (5-HT₁) receptor agonists (triptans), meperidine, or buspirone were excluded.

Overdosage

In the event of overdosage, Tezolin® should be discontinued and general supportive treatment given. Hemodialysis does not result in meaningful removal of Tedizolid from systemic circulation.

Pharmaceutical Precautions

Keep out of the reach of children. Keep in a cool & dry place. Protect from light.

Commercial Pack

Tezolin® tablet: Box containing 6 tablets in 3 x 2's blister strips. Each film coated tablet contains Tedizolid Phosphate INN 200 mg.

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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